

CDER Breakthrough Therapy Designation Requests Received by Fiscal Year

Cohort: July 9, 2012* - September 30, 2015

Data as of December 31, 2015

| Fiscal Year | Total Requests Received | Granted | Denied | Withdrawn |
|--------------------|------------------------------------|----------------|---------------|------------------|
| 2015 | 93 | 32 | 43 | 18 |
| 2014 | 96 | 31 | 51 | 14 |
| 2013 | 92 | 31 | 52 | 9 |
| 2012 | 2 | 1 | 1 | 0 |

* Breakthrough therapy designation was enacted in the Food and Drug Administration Safety and Innovation Act on July 9, 2012.